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Application Serial No. 09/780,041

Figures 3G-3K are objected to for lack of clarity. Applicant hereby deletes Figures 3G-3K. Figures 3G-3K demonstrate the effectiveness of utilizing somatic gene transfer methods and compositions. However, these figures are not essential to describe or enable any embodiments of the subject invention, i.e., they are not essential to patentability. In view of the deletion of the noted figures, the objection to the drawings is obviated. Reconsideration is requested.

Claims 29, 32 and 37 are objected to as pertaining to non-elected subject matter. Claim 29 is cancelled to avoid the Examiner's objection that the claim was directed to non-elected subject matter. As to the Examiner's objection to claims 32 on the same basis, Applicants point out that, due to the use of the conjunction "and" as opposed to "or", claim 32 is actually a species claim to the genus claim 30 on which claim 32 is dependent. As such, Applicants assert that claim 32 does not pertain to non-elected subject matter. The objection to claim 37 is moot, as claim 37 is now cancelled.

Claims 23-38 are rejected under 35 USC § 112, first paragraph, as not meeting the written description requirement. Applicants assert that the amendments to claims 23 and 30 obviate this rejection. While claims 23, 30 and 34 have been amended to clarify that the rodent at issue is a rat or mouse, Applicants maintain that the specification reasonably supports use of the term rodent, and reserve the right to pursue rodent genus claims in related applications. Accordingly, in view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and withdrawal of this 35 USC § 112 written description rejection.

Claims 23-38 are rejected under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey possession of the invention. Applicants note that independent claims 23, 30, and 34 have been amended to recite that the non-human animal at issue is a rat or mouse. Based on the teachings of the subject application, it is clear that the inventors were in possession of the methods recited in claims 23 and 30, and the composition of claim 34, as amended, to produce a neuropathology

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corresponding to a neurodegenerative disease. Accordingly, in view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and withdrawal of this 35 USC § 112 written description rejection.

Claims 23-38 are rejected under 35 USC § 112, first paragraph, as not being enabled. Applicants assert that the amendments to independent claims 23, 30, and 34 obviate this rejection. These claims have been amended to recite that the animal species to which the methods of claims 23 and 30 pertain, and the composition of claim 34 pertain, is a rat or mouse. These amendments have been made in accordance with the guidance provided at pages 5-10 of the outstanding office action. Based on the rationale set forth by the Examiner at such pages, Applicants believe that the scope of all of the rejected claims, as affected by the amendments to claims 23, 30, and 34 are fully enabled. Accordingly, Applicants respectfully request the reconsideration and withdrawal of this 35 USC § 112 enablement rejection.

Further to the above remarks, Applicants provide herewith a copy of the Nacharaju et al. reference which was incorporated by reference into the subject application at page 11. The subject application refers to the Nacharaju et al. reference for examples of types of tau mutants that may be implemented in accord with the method as defined in claim 23 and the method as defined in claim 30. Nacharaju et al. discloses a group of missense and splice-site mutations found on chromosome 17 (FTDP-17), such as, but not limited to, N279K, G272V, V337M, R406W, P301L, and 5' splice-site mutations (+3, +13, +14 and +16), see background. It is not clear from the last office action whether the Examiner is rejecting claims 23, 30 and 34, under 35 USC 112, first paragraph, on the basis that application does not enable tau mutations other than the P301L mutation. First, Applicants believe that such a rejection would be improper irrespective of the teaching of such mutations. With respect to claim 23 and claim 30, Applicants note that they are not claiming a gene comprising a tau mutation that causes neuropathology. Rather, once in possession of such a gene, Applicants are claiming the method of transferring the gene into the brain tissue of a living rat or mouse to achieve the desired neuropathological result. The patentability of the claim is not based on the gene used; it is based

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on how the gene is used, i.e., transferred into the brain of a living rat or mouse to produce a model of a neuropathological condition. This is a situation analogous to the Example 18 described in the Revised Interim Written Description Guidelines, "Process claim where the novelty is in the method steps".

Second, though Applicants' remarks above address the proper standards for written description and enablement to apply to claims 23 and 30, even considering that the gene used is pivotal to patentability, Applicant's teach a representative group of tau mutations that cause neuropathology. Thus, even applying an inappropriate, onerous standard, Applicants' nonetheless satisfy the criteria of enablement and written description.

Claims 23-28 and 34-38 are rejected under 35 USC 112, second paragraph, as being indefinite. The office action states that the recitation of a broad term followed by a more narrow term in the same claim renders claims 23 and 34 indefinite. Applicants traverse. Applicants believe that it is common place to have a generic term in a claim, and then narrowing language that further defines and narrows the generic term. Such a situation arises not infrequently during prosecution when claims are narrowed in response to various rejections. This notwithstanding, claims 23 and 34 have been amended to avoid any indefiniteness possibly created by the purported generic term followed by a narrowing term. Reconsideration of the rejection on this basis is requested.

Claim 35 is said to be indefinite based on the designation of P301L as the aberrant form of tau. Applicants respectfully assert that the amendment to claim 35 obviates this rejection. The nomenclature "P301L" is standard in the field of Neurodegenerative diseases. It is shorthand for describing specific mis-sense mutations (where a mutation in a sequence of nucleotides in DNA changes the codon for the amino acids in the protein gene product). The 'P' refers to the amino acid proline, '301' refers to nucleotide number 301 from the 5-prime end of the tau DNA coding sequence, and 'L' refers to leucine. 'P301L' is shorthand for 'a mutation at position 301 causing leucine to be incorporated in tau instead of proline'. Applicants previously


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submitted a reference (van Slegtenhorst M, Lewis J, Hutton M. The molecular genetics of the tauopathies. Exp Gerontol. 2000 Jul;35(4):461-71) on February 17, 2004 that illustrates the routine use of this nomenclature in the scientific literature for describing a variety of specific known mutations, in this case in the tau gene. The van Slegtenhorst reference, and the references cited therein, clearly establish that the nomenclature "P301L" is well understood and commonly used in the literature. As such, Applicants assert that its use in claim 35 creates no indefiniteness issues. In view of the foregoing remarks, Applicants respectfully request the reconsideration and withdrawal of the rejection on this basis.

The rejection of claim 37 is moot in light of the cancellation of this claim.

All grounds for rejection or objection having been addressed and overcome herein, it is respectfully urged that this application is in condition for allowance. Should the Examiner be of the opinion that there remain valid grounds on which any of the claims as herein amended may be rejected, it is respectfully requested that the undersigned be accorded the courtesy of a telephonic interview to address and overcome any such remaining grounds for rejection.

Respectfully submitted,



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